COMMENT

INCREASING ACCESS TO NALOXONE: ADMINISTRATIVE SOLUTIONS TO THE OPIOID OVERDOSE CRISIS

CHRISTOPHER T. CREECH*

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* J.D. Candidate, 2017, American University Washington College of Law; B.A. Politics, 2011, Oberlin College. Thank you to the staff of the *Administrative Law Review* for your hard work, counsel, and thoughtfulness. This piece is dedicated to the late Jim Gillen, the conscientious, inspiring, and vocal leader of the recovery community in Rhode Island.

INTRODUCTION

Drug overdose is the number one cause of injury-related death in the United States.[1] Approximately 100 Americans die from drug overdoses every day, and prescription opioid drugs—such as Tylenol 3, OxyContin, Vicodin, etc.—accounted for half of the overdose deaths in 2010.[2] In response to the opioid overdose epidemic,[3] the federal government has cracked down on the sale of illicit prescription opioids.[4] Nevertheless, "From 2000 through 2013 . . . drug [overdose] deaths involving heroin nearly quadrupled . . . ."[5] As a response to this staggering statistic, many local and state public health organizations employ naloxone hydrochloride (naloxone) interventions to combat opioid overdose.[6]

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1. *See* Holly Hedegaard et al., *Drug–Poisoning Deaths Involving Heroin: United States, 2000–2013*, NCHS DATA BRIEF NO. 190, Mar. 2015, at 1 (citing Centers for Disease Control and Prevention (CDC) statistics that report 43,982 deaths attributed to drug overdose).

2. *See* Office of Nat'l Drug Control Policy (ONDCP), FACT SHEET: OPIOID ABUSE IN THE UNITED STATES 1 (2014) (citing CDC statistics); *see also 60 Minutes: Heroin in the Heartland*, (CBS television broadcast Nov. 1, 2015), http://www.cbsnews.com/news/heroin-in-the-heartland-60-minutes/ ("Robby got hooked on pain pills prescribed by a dentist after his wisdom teeth were removed.").

3. *See* Oral Testimony at 48:20–48:52, *Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis RECONVENES: Hearing Before the Subcomm. on* Health of the H. Comm. on Energy and Commerce, 114th Cong. (Oct. 20, 2015) [hereinafter Oral Testimony, *Examining Legislative Proposals*], https://energycommerce.house.gov/hearings-and-votes/hearings/examining-legislative-proposals-combat-our-nations-drug-abuse-crisis (statement of Dr. Robert Corey Waller, Chair, Legislative Advocacy Committee of the American Society of Addiction Medicine) ("If it shows up in a community [and] those people . . . have susceptibility from a genetic predisposition . . . it grows just like the disease that we look at on outbreak."); Leonard J. Paulozzi et al., *Vital Signs: Overdose of Prescription Opioid Pain Relievers—United States, 1999–2008*, 60 MORBIDITY & MORTALITY WKLY. REP. 1487, 1489 (2011) (recognizing the "epidemic of overdoses" and linking the rise in prescription opioid-related overdoses to a rise in opioid prescribing).

4. *See, e.g.*, DEA, MULTIPLE DEFENDANTS ARRESTED FOR OPERATING PRESCRIPTION DRUG "PILL MILL" (June 29, 2011), https://www.justice.gov/archive/usao/gan/press/2011/06-29-11.html (illustrating a DEA indictment of individuals running a pill mill disguised as a pain clinic).

5. Hedegaard, *supra* note 1, at 1.

6. *See* Corey S. Davis et al., *Lessons Learned from the Expansion of Naloxone Access in Massachusetts and North Carolina*, 43 J.L. MED. & ETHICS SUPP. 19 (2015) (comparing the efforts of Massachusetts and North Carolina and concluding that—in addition to legal approaches, education, and funding—reclassifying naloxone as an over-the-counter drug is

Naloxone[7] is a safe, easy-to-use, and effective medication that nearly instantaneously reverses opioid overdoses by stopping the effects that heroin and other opioids have on the brain.[8] Medical professionals have used naloxone extensively for decades, and there is a well-established body of evidence showing naloxone's safety and efficacy.[9] In fact, numerous federal administrative agencies are beginning to allocate funds for states to increase access to naloxone. However, these agencies operate within "silos"—separated by jurisdiction and authority with limited communication or cooperation—because they are not statutorily required to collaborate in addressing the overdose epidemic.[10]

In reaction to the growing opioid overdose epidemic, Congress passed the Comprehensive Addiction and Recovery Act (CARA).[11] CARA is remarkable for its breadth and bipartisan support. CARA will provide much needed relief in the form of agency mandates and grant money. Yet, Congress has not addressed the fundamental foundations resulting in the administrative state's failures to respond to the exponential rise in opioid overdoses in an effective and timely manner.[12]

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necessary to successfully combat the opioid overdose epidemic).

7. Naloxone is often also referred to by its brand name, Narcan.

8. *See* OPEN SOCIETY PUBLIC HEALTH PROGRAM, INTRANASAL NALOXONE AND OPIOID OVERDOSE 1 (2012) (examining studies that prove the efficacy of both intramuscular and intranasal naloxone).

9. *See, e.g.*, D.R. Jasinski et al., *The Human Pharmacology and Abuse Potential of N-Allylnoroxymorphone (Naloxone)*, 157 J. PHARMACOLOGY & EXPERIMENTAL THERAPIES 420, 420 (1967) ("no behavioral or physiologic changes were observed during chronic administration and withdrawal of naloxone; however, the ability of naloxone to antagonize the effects of a test dose of morphine persisted."); *see also* J.M. Evans et al., *Degree and Duration of Reversal by Naloxone of Effects of Morphine In Conscious Subjects*, 2 BRITISH J. MED. 589 (1974) ("Naloxone produced a well defined reversal of the respiratory depression . . . and subjective effects of the morphine").

10. Siloing is a criticism of the regulatory apparatus generally. *See* Richard E. Levy & Robert L. Glicksman, *Agency-Specific Precedents*, 89 TEX. L. REV. 499, 511–12 (2011) ("Likewise, centralized regulatory review in the Office of Information and Regulatory Affairs (OIRA) can be understood as an effort to overcome silo thinking within agencies."); *see also* Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1135 (2012) [hereinafter Freeman & Rossi, *Agency Coordination*] ("A key advantage to such delegations may be the potential to harness the expertise and competencies of specialized agencies. But that potential can be wasted if the agencies work at cross-purposes or fail to capitalize on one another's unique strengths and perspectives."). *See generally* JODY FREEMAN & JIM ROSSI, ADMIN. CONF. OF THE U.S., IMPROVING COORDINATION OF RELATED AGENCY RESPONSIBILITIES (June 15, 2012) [hereinafter FREEMAN & ROSSI, ADMIN. CONF.] (adapted from Freeman & Rossi, *Agency Coordination*).

11. *See* Comprehensive Addition and Recovery Act, S. 524, 114th Cong. (2016) (enrolled bill).

12. *See generally* Freeman & Rossi, *Agency Coordination*, *supra* note 10, at 1139 (explaining

This Comment argues that three administrative actions are necessary to address the underlying causes of the opioid overdose epidemic. First, the U.S. Food and Drug Administration (FDA) should act affirmatively and reclassify naloxone as an over-the-counter drug. Second, in appropriating funds for the purchase of naloxone, Congress should encourage intra-agency cooperation with an eye towards reducing the effect of agency siloing. Third, the President, through executive order, should establish the Inter-Agency Opioid Overdose Prevention Taskforce. Members of the Taskforce should sign a memorandum of understanding (MOU), spurred by executive memorandum or order, in which they agree to share and coordinate in the production of best practices, data sets, regulations, and grant programs.

Part I of this Comment will reveal the historical perspective necessary to understand the recent resurgence of heroin use. Part II will discuss naloxone's efficacy and current legal status. Based on this paradigm, Part III outlines how the Office of National Drug Control Policy (ONDCP), the Centers for Disease Control (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA) have begun expanding their work to increase access to naloxone and how the three agencies operate within silos. Part IV will tie together the previous Parts and outline how states have found creative and highly functional solutions to overcome the limitations imposed by naloxone's current legal status.

After establishing the foundations of the current naloxone regime, Part V will study how Congress has begun to turn its attention to arming several federal administrative agencies with the authority and funding to support the work of the states. As a general matter, CARA and the proposed bills presented in Part V call for creating interagency taskforces with limited scopes, creating grant programs administered by individual agencies, and altering the legal status of naloxone. In conclusion, Part VI recommends the creation of a new naloxone distribution regime.

I. HOW DID WE GET HERE AND WHAT IS NALOXONE?

Over the last decade, the emergence of widespread opioid addiction has been treated as a law enforcement problem.[13] One successful facet of the

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that the redundant authority of congressional committees has led to redundant agency authority, "in which numerous committees frequently share oversight or budgetary functions as a way of maximizing the ability of members to advance the interests of constituents and thus their own prospects for reelection.").

13. *See* Scott Burris et al., *Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone to Prevent Opioid Overdose*, 1 DREXEL L. REV. 273, 277 (2009) ("Part of the overdose

federal and state law enforcement response to prescription opioid addiction has been to crack down on pill mills and on illicit prescribing.[14] While the availability of illegally obtained prescription opioids shrank, the number of addicted individuals seeking opioids persisted.[15] In turn, opioid-addicted individuals sought the cheaper and more easily accessible heroin.[16] Consequently, the national crackdown on prescription pill mills has been met with an increase in heroin trafficking.[17] Regrettably, overdose deaths have skyrocketed because judging the potency of street drugs is often impossible and opioid users either put misplaced trust in their dealers or misjudge their tolerance.[18]

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epidemic is a side effect of the War on Drugs."); *see also* Katharine Q. Seelye, *In Heroin Crisis, White Families Seek Gentler War on Drugs*, N.Y. TIMES (Oct. 30, 2015) (positing that the demographic makeup of those overdosing from heroin—predominantly white—compared to the crack epidemic—predominantly black—has produced a greater political backlash against the status quo of "zero tolerance and stiff prison sentences").

14. *See* ONDCP, EPIDEMIC: RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS 2 (2011) (arguing that the ONDCP's effort to fund law enforcement agencies through anti-drug taskforces will help to "shut down" pill mills); *see also* Leonard Paulozzi et al., *Prescription Drug Overdose—a U.S. Epidemic*, 61 MORBIDITY & MORTALITY WKLY. REP. 10, 11 (2012) ("Laws against such 'pill mills' as well as laws that require physical examinations before prescribing might help reduce the diversion of these drugs for nonmedical use.").

15. *See* Theodore J. Cicero et al., *Effect of Abuse-Deterrent Formulation of OxyContin*, 367 NEW ENG. J. MED. 188, 189 (discovering that while a new abuse-deterrent OxyContin successfully forestalled use of OxyContin, "66% indicated a switch to another opioid, with 'heroin' the most common response"). *See generally* Thomas Kosten et al., *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 ADDICTION SCI. & CLINICAL PRACTICE 13, 13 (2002) ("Brain abnormalities resulting from chronic use of heroin, oxycodone, and other morphine-derived drugs are underlying causes of opioid dependence . . . and addiction.").

16. *See* Evan Perez et al., *Ready Access, Low Cost, Pill-like High: Heroin's Rise and Fatal Draw*, CNN (Feb. 4, 2014, 7:45 AM), http://www.cnn.com/2014/02/02/us/heroin-use-rising/ (explaining that individuals with addiction seek out heroin after prescription opioids become more expensive because heroin is cheaper, provides the same high, and is readily available); *see also* NAT'L INST. ON DRUG ABUSE, HHS, DRUG FACTS: HEROIN 1 (2014) ("Prescription opioid pain medications such as Oxycontin and Vicodin can have effects similar to heroin . . . .").

17. *See* DEA, NAT'L HEROIN THREAT ASSESSMENT SUMMARY 2 (Apr. 2015) (connecting the rise in demand of heroin to both the availability of heroin and the number of prescription opioid users switching to heroin); *see also* David DiSalvo, *Why Is Heroin Abuse Rising While Other Drug Abuse Is Falling?*, FORBES (Jan. 14, 2014, 10:21 PM), http://www.forbes.com/sites/daviddisalvo/2014/01/14/why-is-heroin-abuse-rising-while-other-drug-abuse-is-falling/#33302cfa60fd ("The reason may come down to basic economics: illegally obtained prescription pain killers have become more expensive and harder to get, while the price and difficulty in obtaining heroin have decreased.").

18. *See* Mabel Frias et al., *Acetyl Fentanyl Overdose Fatalities—Rhode Island, March–May 2013*, 62 MORBIDITY & MORTALITY WKLY. REP. 685, 703 (2013) ("Acetyl fentanyl, a synthetic opioid . . . is up to five times more potent than heroin as an analgesic.").

An opioid overdose occurs when opioids—whether legal or illicit prescription drugs, or heroin—overwhelm the opioid receptors in the brain, causing respiratory suppression and ultimately death.[19] Naloxone administered intramuscularly or intranasally can prevent most opioid overdoses.[20] Naloxone is an opioid receptor antagonist, with no agonist properties.[21] Naloxone has no potential for abuse because it has no effect absent the presence of opioids.[22] Efforts to arm bystanders—laypeople who may encounter an opioid overdose—with naloxone have been successful in curbing the overdose epidemic.[23]

II. CURRENT NALOXONE DISTRIBUTION REGIME

The recent efforts of government actors take place within the framework created by naloxone's current legal status as a prescription drug. Despite having no potential for abuse, naloxone is only available as a prescription.[24] Thus, at the core of the naloxone distribution regime are the FDA regulations effecting the system.[25] The FDA regulates naloxone under the

19. *See* Ayman Fareed et al., *Illicit Opioid Intoxication: Diagnosis and Treatment*, 5 SUBSTANCE ABUSE: RESEARCH AND TREATMENT 17, 19 (2011) ("Death is usually from respiratory depression.").

20. *See* Tinka M. Piper et al., *Overdose Prevention for Injection Drug Users: Lessons Learned from Naloxone Training and Distribution Programs in New York City*, 4 HARM REDUCTION J. 3, 3 (2007) ("Many of these deaths are preventable because opiate overdoses can be quickly and safely reversed through the injection of Naloxone.").

21. An agonist is a chemical that produces a biological response by binding to a neurotransmitter receptor. An antagonist is a chemical that blocks or dampens an agonist-created response by binding stronger to the same receptor. *See* FDA, 3482803, HIGHLIGHTS OF PRESCRIBING INFORMATION EVZIO 1 (2014) (determining that Evzio, a brand name for naloxone, "is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose").

22. *See* HARM REDUCTION COALITION, *Understanding Naloxone*, http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/ (last visited June 9, 2016) ("Naloxone only works if a person has opioids in their system; the medication has no effect if opioids are absent.").

23. *See* Alexander Y. Walley et al., *Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis*, 346 BMJ 1 (2013) ("training potential bystanders to prevent, recognize, and respond to opioid overdoses . . . is an effective intervention."); *see also* FDA, ROLE OF NALOXONE IN OPIOID OVERDOSE FATALITY PREVENTION 142–43 (Apr. 12, 2012) [hereinafter FDA, ROLE OF NALOXONE] ("The response includes naloxone, . . . calling 911, rescue breathing, and staying with the person until they are alert or help arrives.").

24. *See* ERIN BAGALMAN, CONG. RESEARCH SERV., IN10031, HEROIN AND PRESCRIPTION OPIOID ABUSE: ACCESS TO NALOXONE TO TREAT OVERDOSE 2 (2014) (discussing naloxone's status and how that status could be altered through provisions of the Federal Food, Drug, and Cosmetic Act (FD&CA)).

25. That is not to say that other legal restrictions do not affect the distribution of

Federal Food, Drug, and Cosmetic Act (FD&CA).[26] In 1971, the FDA approved the production of naloxone under the name Narcan by both Endo Pharms and Bristol Myers Squibb through a New Drug Application (NDA).[27] The NDA process is a formal adjudicatory-like procedure through which the FDA grants or denies pharmaceutical manufacturers consent to produce a medication or device.[28]

During an FDA public meeting in April 2012, representatives from the FDA, Department of Health and Human Services (HHS), and the National Institute on Drug Abuse (NIDA) discussed whether the FDA should reclassify naloxone as an over-the-counter drug and whether the FDA should formally approve intranasal naloxone.[29] That meeting showed broad support for reclassifying naloxone;[30] yet, the FDA has not acted.[31] It

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naloxone. For example, naloxone is manufactured from noroxymorphone, a controlled substance. *See* 80 C.F.R. 193 (2015) (establishing the 2016 production quota of noroxymorphone as 17,500,000 grams—the same as 2015). Noroxymorphone is subject to quotas set by the Drug Enforcement Agency (DEA) and any substantial increase in production would need to be met with an increase in that quota. *See* 21 U.S.C. 826 (2012) (requiring the Attorney General to aggregate production quotas for schedule I and II substances); *see also* 28 C.F.R. 0.100 (2012) (designating scheduled substance quota authority to the DEA). The DEA's determination is subject to a substantial evidence review and, given strong government interest in preventing overproduction of controlled substances, is unlikely to be overturned through judicial review. *See* W. Fher Labs. v. Levi, 529 F.2d 325, 328 (1st Cir. 1976) (giving heavy weight to previous production quotas and sales).

26. *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b) (2012) (providing statutory authority for the FDA's regulation of prescription drugs).

27. *Drug Details Narcan*, FDA (2015), http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (last visited June 9, 2016) (search for "Narcan"); *see* 21 U.S.C. § 355(b) (2012) (outlining statutory requirements for the New Drug Application (NDA) process); *see also infra* part VI.A.1.

28. *See New Drug Application (NDA)*, FDA (Mar. 29, 2016), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited June 9, 2016) ("The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.").

29. *See* FDA, ROLE OF NALOXONE, *supra* note 23, at 7 ("[T]he question is, what can be done to further the use of [naloxone], if appropriate, among illicit drug users and for those who are on long-term narcotics, for example, those with chronic cancer pain.").

30. *See* Maia Szalavitz, *Naloxone Debate: FDA Hear Testimony About Making an Overdose Antidote Nonprescription*, TIME (Apr. 13, 2012) (reporting that the overwhelming majority of commenters and panel members supported the idea of reclassifying naloxone and that any opposition was unfounded).

31. The exact reason for FDA inaction is unknown. A combination of politics, stigma of addiction, and a misunderstanding of naloxone itself have likely all contributed to naloxone remaining a prescription drug. *See* Piper, *supra* note 20, at 4 (asserting that the opposition to expansion of naloxone access is not the safety of naloxone itself but an unfounded assumption that heroin users will use more drugs because they do not have to

is important to note that the FDA acted on the latter recommendation when it approved intranasal naloxone through a fast-track procedure.[32]

It is not clear whether the FDA will revisit naloxone's prescription-only classification. Recently, HHS released a comprehensive summary of HHS's initiatives and its sub-agencies' initiatives, including the FDA, which addressed the opioid overdose epidemic.[33] The report reiterated the FDA's role of "encourag[ing] innovation" among manufacturers, but it did not mention an initiative to review naloxone's classification.[34]

III. CURRENT FEDERAL RESPONSES TO OPIOID OVERDOSE

Viewing opioid addiction and overdose from a public health perspective, the current naloxone distribution regime is deeply flawed.[35] Through the ONDCP, SAMHSA, and the CDC, the federal government largely has acted to support the work of states through guidance and funding.[36] The

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worry about dying from overdose).

32. Press Release, FDA, FDA Moves Quickly to Approve Easy-to-Use Nasal Spray to Treat Opioid Overdose (Nov. 18, 2015), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm (reporting that the FDA approved intranasal naloxone and stating that intranasal naloxone is easier for individuals without medical training to administer because it "does not require assembly and delivers a consistent, measured dose"). *See generally* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105–115, 111 Stat. 2296 (1997) (defining fast tracking as a statutory mechanism that allows the FDA to increase the number of meetings with a designee, faster correspondence between the FDA and the designee, priority review of the designee's application, and a level of appeal beyond the typical reviewing board).

33. HHS, OPIOID ABUSE IN THE U.S. AND HHS ACTIONS TO ADDRESS OPIOID-DRUG RELATED OVERDOSES AND DEATHS (Mar. 26, 2015).

34. *Id.* at 4.

35. For example, lack of access to naloxone has driven heroin users to seek naloxone through community-funded efforts facilitated through online support communities such as reddit.com/r/opiates. *See* jelllly, *Another life saved by Tracey*, R/OPIATES (Feb. 25, 2015 9:03:28), https://www.reddit.com/r/opiates/comments/2uutcf/another_life_saved_by_tracey/; *see also* Andrew McMillen, *The Heroin Heroine of Reddit*, BACKCHANNEL (July 21, 2015), https://backchannel.com/the-heroin-heroine-of-reddit-a2fffcc2a25b#.tf20szvnu (profiling Tracey Helton who connects with individuals online to make naloxone and clean needles available to a wider population).

36. *See, e.g.*, SAMHSA, OPIOID OVERDOSE PREVENTION TOOLKIT, HHS Publ'n No. (SMA) 16-4742 (2016), http://store.samhsa.gov/shin/content//SMA16-4742/SMA16-4742.pdf (providing administrative and technical guidance for state and local governments and organizations seeking to implement naloxone programs); CALEB BANTA-GREEN, EXEC. OFFICE OF THE PRESIDENT, GOOD SAMARITAN OVERDOSE RESPONSE LAWS: LESSONS LEARNED FROM WASHINGTON STATE, https://www.whitehouse.gov/blog/2013/03/29/good-samaritan-overdose-response-laws-lessons-learned-washington-state (2013) (encouraging states to adopt cost-neutral legislation to combat the opioid overdose epidemic).

federal government does not provide funding for the exclusive purpose of increasing access to and use of naloxone.[37] However, the ONDCP, CDC, and SAMHSA have issued policy statements, which allow grant awardees to purchase naloxone for first responders, law enforcement officers, and public health organizations.[38]

The ONDCP, CDC, and SAMHSA operate within silos but have largely similar missions—to protect the health, safety and welfare of the public—but their methods and tools differ in important ways. Each agency, given their relative disciplines, will face mutual challenges in coordinating their operational activities including: funding, administration, data collection, and the creation of best practice guidelines. This Part will analyze each agency's role in the current naloxone distribution regime.

A. Office of National Drug Control Policy

The Anti-Drug Abuse Act of 1988 established the ONDCP to set drug control priorities, implement a national strategy, and certify Federal drug-control budgets.[39] Executive Order 12,880 provided that the ONDCP was to lead the Executive Branch drug abuse prevention policy "with the goal of reducing the production, availability, and use of illegal drugs."[40] Furthermore, while establishing the President's Council on Counter-Narcotics through Executive Order 12,992, President Clinton characterized the Director of the ONDCP as the "senior drug control policy official."[41]

One of the flagship programs of the ONDCP is the High Intensity Drug Trafficking Area (HIDTA) program. The stated goal of the HIDTA is to disrupt the market for illegal drugs by dismantling or disrupting drug trafficking and money laundering organizations.[42] These goals are "enforcement-centric" and endeavor to create a "united front" by building taskforces of local, county, state, and federal law enforcement agencies.[43]

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37. Although, a number of agencies have begun to redirect existing grant funding towards funding naloxone programs. *See* discussion *infra* Part III.A–C.

38. *See id.*

39. *See* Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, 102 Stat. 4181 (1988) (establishing the ONDCP and outlining the scope of the ONDCP's duties).

40. Exec. Order No. 12,880, 3 C.F.R., 1993 Comp., 677 (1993).

41. Exec. Order No. 12,992, 3 C.F.R., 1996 Comp., 170–71 (1996).

42. EXEC. OFFICE OF THE PRESIDENT, ONDCP, HIDTA PROGRAM, POLICY AND BUDGET GUIDANCE 2–3 (2012).

43. *See* Julie Sutton et al., *Oregon High Intensity Drug Trafficking Area (HIDTA) Program: Threat Assessment, Counter-Drug Strategy, Position, and Conclusion*, 91 OR. L. REV. 1265, 1267–70 (2013) (arguing that the role of the HIDTA program in "control and outright prohibition of

As a potential marker that the administration is moving away from a strict law enforcement strategy to a more holistic community-based and mental health approach, the ONDCP plans to provide funding for the purchase of naloxone through the HIDTA program.[44] Framing the ONDCP's new strategy is thirteen years of exponential growth in the number of deaths from heroin overdose.[45] In particular, the ONDCP will focus on the regions hardest hit by the overdose epidemic—Appalachia, New England, Philadelphia/Camden, New York/New Jersey, and Washington/Baltimore.[46] Critics of the White House's new strategy say that it reinforces the status quo of the War on Drugs because the goals of the HIDTA program remain centered upon supply reduction.[47] Regardless of whether those criticisms are well-founded,[48] traditionally the role of the HIDTA has been strictly law enforcement.[49] The ONDCP's announcement is an early sign that community health goals of referral-first and harm reduction are beginning to find their way into mainstream law enforcement.

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dangerous drugs" has been effective in deterring illicit drug use).

44. *See White House Drug Policy Office Funds New Projects in High Intensity Drug Trafficking Areas*, EXEC. OFFICE OF THE PRESIDENT (Aug. 17, 2015) [hereinafter *New Projects in HIDTA*], https://www.whitehouse.gov/the-press-office/2015/08/17/white-house-drug-policy-office-funds-new-projects-high-intensity-drug; *see also* FACT SHEET: OBAMA ADMINISTRATION ANNOUNCES PUBLIC AND PRIVATE SECTOR EFFORTS TO ADDRESS PRESCRIPTION DRUG ABUSE AND HEROIN USE, OFFICE OF THE PRESS SECRETARY (Oct. 21, 2015), https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector (last visited Mar. 20, 2016) ("The President's Fiscal Year 2016 budget includes . . . new investments aimed at addressing . . . access to the overdose-reversal drug naloxone.").

45. Hedegaard, *supra* note 1, at 1 (providing that heroin overdose nearly quadrupled, "from 0.7 deaths per 100,000 in 2000 to 2.7 deaths per 100,000 in 2013").

46. *New Projects in HIDTA*, *supra* note 44.

47. *See White House Opiate Overdose Program Announced Today Is One Step Forward, Two Steps Back*, DRUG POLICY ALLIANCE (Aug. 17, 2015), http://www.drugpolicy.org/news/2015/08/white-house-opiate-overdose-program-announced-today-one-step-forward-two-steps-back (last visited Mar. 20, 2016) (arguing that the HIDTA program is a part of the problem because law enforcement-centric efforts ignore the public health issue behind the opioid overdose crisis and calling for the lifting of the statutory ban on using HIDTA funding for substance addiction treatment).

48. *See generally* Steven Mufson et al., *White House Announces New Steps to Combat Heroin, Prescription Drug Abuse*, WASH. POST (Oct. 21, 2015) ("The efforts, which President Obama unveiled at a forum here, are likely to have a modest effect on the steep increase in heroin and prescription drug overdoses . . . .").

49. *See* Sutton, *supra* note 43 (providing that ONDCP seeks to prevent drug trafficking through both enforcement and facilitation).

B. Substance Abuse and Mental Health Services Administration

Congress created SAMHSA as an agency within HHS in 1992 with a limited scope: to administer the Substance Abuse Prevention and Treatment Block Grant (SABG) program, and to improve the quality and availability of treatment services.[50] Where the ONDCP seeks to reduce the supply of opioids, SAMHSA seeks to reduce the demand by funding substance addiction treatment programs. Primarily, SAMHSA analyzes and studies how best to distribute block grant funds for the treatment of drug addiction.[51] To do so, SAMHSA works closely with the National Institutes of Health (NIH), the Department of Education, and the CDC.[52] Despite overlapping enterprises, such as SAMHSA's SABG program's focus on substance addiction treatment, there are few statutory requirements that ensure that these agencies collaborate.[53]

The SABG provides the majority of all funding for state substance addiction treatment programs.[54] The SABG is a formula based grant authorized by the Public Health Service Act, which requires the HHS Secretary to create regulations as a precondition to making funds available to states and other grantees.[55] To highlight SAMHSA's focus on funding treatment, SAMHSA's Community Mental Health Services Block Grant, which funds mental health treatment in general, accounts for 2–3% of state mental health agencies' budgets.[56] Through SAMHSA's 2000

50. *See* ADAMHA Reorganization Act, 102 Pub. L. No. 321 § 501(d) (1992) (amending the Public Health Service Act, 42 U.S.C. § 290aa (1988)) (providing SAMHSA's authority through the SABG to improve treatment and related services to individuals with substance abuse and mental illness).

51. *See HHS Drug Treatment Support: Is SAMHSA Optimizing Resources?: Hearing Before the Subcomm. on* Criminal Justice, Drug Policy and Human Res. of the H. Comm. on Gov't Reform, 106th Cong. 116–19, 165 (2000) [hereinafter Statement, *HHS Drug Treatment Support*] (statement of Rep. Edolphus Towns) (discussing the role of HHS, primarily to administer grants, and the grant programs that HHS administers, primarily substance abuse related).

52. *See* RAMYA SUNDARARAMAN, CONG. RESEARCH SERV., RL33997, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA): REAUTHORIZATION ISSUES 7 (2008) (discussing where various agencies' missions overlap with SAMHSA's mission).

53. *See id.* (explaining that statutory requirements mandating other agencies to work closely with SAMHSA would improve quality and efficiency of SAMHSA services).

54. *Substance Abuse Prevention and Treatment Block Grant*, SAMHSA (Feb. 2, 2002), www.samhsa.gov/grants/block-grants/sabg (last updated Feb. 2, 2015).

55. 42 U.S.C. § 300x-1(c)(2)–(3) (2012).

56. *See* SUNDARARAMAN, *supra* note 52, at 1 (determining that this distinction reflects SAMHSA's and the states' traditional role in the fields of mental health and substance abuse).

reauthorization, Congress expanded SAMHSA's focus on youth at risk due to violence, substance abuse, or mental illness.[57] Recently, SAMHSA has advised that block grant recipients can use SABG funds to purchase and distribute naloxone.[58]

C. Centers for Disease Control and Prevention

The CDC, an agency within HHS, is the nation's authority on epidemiology and the prevention of infectious diseases.[59] Until the CDC was asked to lead the response to the Acquired Immune Deficiency Syndrome (AIDS) crisis, the CDC largely focused on developing practical guidelines to prevent the transmission of infectious disease.[60] The CDC's role has since expanded to include non-research based grants and the issuing of non-binding policy guidelines.[61] The CDC's non-research based grants seek to "identify and control a health problem or improve a public health program or service."[62]

The CDC's new program, Prescription Drug Overdose Prevention for States, provides support and funding for state health departments to enhance their prescription drug monitoring programs.[63] States could potentially use these funds to finance the purchase of naloxone.[64] Similar to

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57. *See* Children's Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000) (codified at 42 U.S.C. § 201) (reauthorizing SAMHSA's budget).

58. *See* SAMHSA, EXPANSION OF NALOXONE IN THE PREVENTION OF OPIOID OVERDOSE FAQS at 1.

59. *See* Elizabeth W. Etheridge, et al., *History of the CDC*, 45 MORBIDITY & MORTALITY WKLY. REP. 526, 526 (1996) (arguing that the CDC is recognized around the world as synonymous with public health).

60. *See id.* at 527–30 (discussing the CDC's role before and after the Acquired Immune Deficiency Syndrome (AIDS) crisis when the "CDC helped lead the response to this epidemic, including characterization of the syndrome and defining risk factors for disease").

61. *See* 42 U.S.C. § 241(a)(1) (2012) ("the Secretary is authorized to . . . collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities"); *see also* Paula E. Berg, *When the Hazard is Human: Irrationality, Inequity, and Unintended Consequences in Federal Regulation of Contagion*, 75 WASH. U. L.Q. 1367, 1372–75 (1997) (providing a brief history of the CDC and stating that the CDC's guideline publishing authority is limited by its governing statute).

62. CDC, HHS, CDC–SA–2010–02, DISTINGUISHING PUBLIC HEALTH RESEARCH AND PUBLIC HEALTH NONRESEARCH 3 (2010).

63. *See Prescription Drug Overdose Prevention for States*, CDC (2015), http://www.cdc.gov/drugoverdose/states/state_prevention.html (updated Mar. 15, 2016) ("With this funding received in September 2015, participating states began executing and evaluating prevention strategies to improve safe prescribing practices and prevent prescription drug overuse, misuse, abuse, and overdose.").

64. *See Promising State Strategies*, CDC, http://www.cdc.gov/drugoverdose/policy/index.html (last updated March 23, 2016).

SAMHSA's SABG, the CDC's issuing of funds for the purchase of naloxone is ancillary to the grant's main thrust, to reduce the supply of illicit opioids.[65]

IV. STATE RESPONSES TO OPIOID OVERDOSE

State and local governments have led community-based health responses as a means to prevent opioid overdose.[66] The ONDCP, SAMHSA, and the CDC—through the HIDTA program, the SABG, and the Prescription Drug Overdose Prevention for States program, respectively—have made it a priority to support the work of the states. Likewise, state laws are diverse and creative in filling the gaps left by federal regulation.[67] In particular, states have focused on passing liability-limiting legislation.[68]

There are various types of legislation that states have passed in an attempt to increase the use of naloxone. For example, many states and municipalities aim to increase access for first responders and law enforcement by reducing civil and criminal liability for those groups.[69] Good Samaritan laws encourage bystanders at the scene of an opioid overdose to call the police by removing criminal liability for misdemeanor drug and paraphernalia possession.[70] In addition, Good Samaritan laws remove civil liability for bystanders, police officers, and first responders who

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65. *See id.*

66. *See* NAT'L ASSOC. OF STATE ALCOHOL AND DRUG ABUSE DIRS., OVERVIEW OF STATE LEGISLATION TO INCREASE ACCESS TO TREATMENT FOR OPIOID OVERDOSE (2013) (detailing the "variety of public health tools available for States to address fatal opioid drug overdose").

67. Some states, like Ohio, go so far as to allow pharmacists and pharmacy interns to dispense naloxone without a prescription. *See* OHIO REV. CODE ANN. § 4729.44 (LexisNexis 2015) (providing essentially limited behind-the-counter naloxone for Ohio residents); *see also* OHIO STATE BD. OF PHARMACY, NALOXONE RESOURCES 7 (providing resources for a variety of professionals to help them dispense naloxone).

68. *See also* Kelsey Bissonnette, Note, *Anti-Death Legislation: Fighting Overdose Mortality from a Public Health Perspective*, 23 TEMP. POL. & CIV. RTS. L. REV. 451, 460 (2014) (asserting that state legislation largely focuses on: "laws that give limited immunity from prosecution for overdose witnesses who call 911, and laws that enable laypersons to administer naloxone to overdose victims."). *See generally* Davis, *supra* note 6, at 2 (detailing the impetus for and the status of state efforts to reduce liability to increase the use of naloxone during opioid overdoses).

69. *See* Davis, *supra* note 6, at 20 (outlining state EMS laws and the National Highway Traffic Safety Administration's guidelines and determining that all levels of EMS providers should be trained to administer naloxone).

70. *See* Bissonnette, *supra* note 68, at 451 ("The idea behind these laws is that sometimes people do not call 911 when they observe an overdose because they are afraid that they will be taken to jail, or face other legal consequences as a result. If implemented nationwide, these laws could have a significant effect.").

administer naloxone in the event of an overdose, which encourage these groups to purchase and use naloxone.[71] State health organizations have clarified physician liability because physicians may hesitate to prescribe naloxone if state law is unclear.[72] Third-party prescribing—allowing a friend or family member to administer naloxone to an individual overdosing—is often protected with certain caveats.[73]

States continue to implement new laws to encourage greater access to, and use of, naloxone,[74] but the diversity of state-level legislation exemplifies the difficulties created by the current naloxone regime.[75] For example, the State of Rhode Island: Department of Health has issued a number of emergency regulations, one of which allows health care professionals to provide a non-patient-specific prescription of naloxone.[76] Many states are operating under similar collaborative agreements that allow pharmacists to issue prescriptions for naloxone on behalf of physicians.[77] These

71. *See Drug Overdose Immunity and "Good Samaritan" Laws*, NAT'L CONFERENCE OF STATE LEGISLATURES (2015) (explaining that as of April 12, 2016, thirty-five states and the District of Columbia have passed Good Samaritan laws to make it easier for medical professional to dispense naloxone).

72. *See* Burris et al., *supra* note 13, at 278 ("Because health care providers have to be involved, naloxone programs must deal with concerns about liability, which among doctors can be powerful even when they are not well-founded in fact.").

73. *See, e.g.*, OHIO REV. CODE ANN. § 2925.61(B)(1)–(3) (LexisNexis 2015) (providing immunity for third-party prescribers only if the naloxone was obtained from a licensed health professional, the naloxone is administered to an individual apparently experiencing overdose, and the administering party calls emergency services); KY. REV. STAT. ANN. § 217.186(2) (LexisNexis 2015) (authorizing third-party administration of naloxone only if the third-party is instructed to "immediately notify a local public safety answering point").

74. *See, e.g.*, Jim Newton, *Lake County Opioid Initiative: Heroin Law Will 'Save so Many Lives'*, CHI. TRIB. (Sept. 9, 2015 6:26 PM), http://www.chicagotribune.com/news/local/breaking/ct-lns-illinois-heroin-law-lake-county-st-0910-20150909-story.html (outlining Illinois's newest naloxone statute that allows pharmacies to dispense naloxone).

75. For example, Maryland allows naloxone to be obtained without a prescription so long as they have been trained by a state health official, while Rhode Island allows individuals to obtain a prescription for naloxone from a physician—that they may never meet—after they receive training from a community health worker. *See* MD. CODE ANN., HEALTH-GEN. §§ 13-3107, 3110 (LexisNexis 2016); 16 R.I. GEN. LAWS § 16-21-35 (2016).

76. *See* RHODE ISLAND DEP'T OF HEALTH, R23-1-OPIOID, RULES AND REGULATIONS PERTAINING TO OPIOID OVERDOSE PREVENTION 2 (2014) ("[O]ne prescriber is now able to issue a non-patient-specific order to numerous organizations, such as police departments, allowing for increased access to the opioid antagonist Naloxone.").

77. Linda Borg, *By End of August, CVS Will Offer Narcan Without Prescription to Counter Opiate Overdoses*, PROVIDENCE J. (Aug. 23, 2014), http://www.providencejournal.com/article/20140823/LIFESTYLE/308239953 (explaining that in Rhode Island, Walgreens Pharmacy and Dr. Josiah Rich have entered into a collaborative agreement that allows pharmacists to prescribe naloxone on his behalf after briefly training recipients).

agreements allow people to more easily purchase naloxone; however, co-pays, stigma, and lack of awareness prevent the programs from being fully realized. States have been creative in overcoming some of the hurdles imposed by prescription-only naloxone; the federal government has been criticized for being slow to address the problems inherent in prescription-only naloxone.[78]

V. PROPOSED CHANGES TO THE CURRENT NALOXONE DISTRIBUTION REGIME

CARA along with a number of other opioid addiction bipartisan bills represent a sharp change in political climate. The common ground between political ideologies are intersecting concerns over law enforcement's and the public health sector's capacity to respond to the opioid overdose crisis. A number of enacted and proposed provisions address access to naloxone.

This Part outlines and discusses how various bills will change and complement the roles of the agencies they would affect. Subpart A will discuss CARA's provisions relevant to this Comment. Subpart B will discuss bills that propose the creation of taskforces as well as grant programs for the purchase of naloxone. Subpart C discusses the Opioid Overdose Reduction Act, which would reduce civil liability for professionals and laypeople who administer naloxone during an overdose. Finally, Subpart D comments on two current bills that call for the FDA to review naloxone's status as a prescription drug.

A. Comprehensive Addiction and Recovery Act of 2015

CARA was passed by both the House and Senate after being introduced by Senator Sheldon Whitehouse (D-RI) and Representative Jim Sensenbrenner (R-WI).[79] CARA became an omnibus bill for addiction recovery and overdose prevention provisions.[80] This Subpart will focus on

78. *See* Richard Knox, *Overdose Rescue Kits Save Lives*, NPR (January 2, 2008), http://www.npr.org/templates/story/story.php?storyId=17578955 (showing that until recently the ONDCP has opposed the use of naloxone by non-medical professionals and has argued that naloxone may encourage drug abusers to keep using heroin).

79. *See* Comprehensive Addition and Recovery Act, S. 524 § 101, 114th Cong. (2016) (enrolled bill).

80. Some additional provisions of CARA would create: the National Taskforce on Recovery and Collateral Consequences that would recommend legislative and regulatory changes related to individuals with substance addiction disorder and drug convictions; a national opioid abuse education program; treatment programs as alternatives to

five provisions of CARA: establishment of a taskforce to develop best practices for opioid prescribing;[81] creation of a demonstration grant that would arm law enforcement agencies with naloxone;[82] expansion of access to naloxone for patients at VA hospitals;[83] creation of grants to increase co-prescribing of naloxone with prescription opioids;[84] and, creation of grants to increase access to naloxone at pharmacies.[85]

Title I of CARA creates the Pain Management Best Practices Inter-Agency Task Force (Pain Management Taskforce) to develop best practices standards for prescribing opioid prescriptions overseen by the Secretary of HHS.[86] After a public comment period and reviewing existing pain management research and ongoing efforts at the state and local levels, the Pain Management Taskforce would recommend best practices for opioid prescribing.[87] The Pain Management Taskforce would also be required to submit reports to Congress outlining dissemination strategy and other recommendations for applying the best practices.[88] The Pain Management Taskforce would consist of representatives of thirteen government agencies[89] and various professional groups.

Title II of CARA establishes a grant administered by the United States Attorney General.[90] Most important to this Comment, the grant makes money available to equip first responders with naloxone, train first responders to administer naloxone, and establish protocols to refer individuals to treatment.[91] The grant also provides funding to expand

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incarceration; funding for medication assisted treatment programs; and state demonstration grants to fund public health programs. *See* S. 524.

81. *Id.* § 101.

82. *Id.* § 202.

83. *Id.* § 601.

84. *Id.* § 107.

85. *Id.* § 110.

86. *Id.* § 101; *see* Deborah Dowell, et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States*, 2016, 65 MORBIDITY & MORTALITY WKLY. REP. 1, 23 (2016) (recommending that prescribers consider co-prescribing naloxone to both patients receiving an opioid prescription and those patients' household members).

87. S. 524 § 101 (the taskforce will provide "recommendations on how to apply best practices . . . to improve prescribing practices at medical facilities.")

88. *Id.* § 101(e)(1)–(3).

89. *See id.* § 101(b) (listing: HHS; VA; FDA; Department of Defense; Drug Enforcement Administration; CDC; Health Resources and Services Administration; Indian Health Service; National Academy of Medicine; NIH; ONDCP; SAMHSA; and Office of Women's Health).

90. *Id.* § 202.

91. *Id.* § 202(g)(5) (providing grants for "the research, training, and naloxone supply needs of law enforcement and first responder agencies.").

treatment alternatives to incarceration,[92] facilitate collaboration between state criminal justice agencies and state substance abuse systems, investigate unlawful distribution of opioids, expand prescription drug monitoring programs, and expand prescription takeback programs.[93]

Title IX of CARA was originally introduced in the Senate by Senator Tammy Baldwin (D-WI) as the Jason Simcakoski Act, named in honor of U.S. Marine Veteran Jason Simcakoski who died of an overdose after being prescribed thirteen different medications, including opioids. Subtitle A emphasizes improving the Department of Veterans Affairs (VA) response to opioid addiction in the military veteran community.[94] The veteran community, due to high rates of painful medical conditions, is at a high risk for opioid use.[95] In summary, Title IX would provide new guidelines for the management of opioid therapy, improve opioid safety measures, establish a pain management working group and board, and establish an Office of Patient Advocacy within the VA.[96]

Of particular note, the Jason Simcakoski Act would require the Director of the VA to expand the VA's Overdose Education and Naloxone Distribution (OEND) program by equipping each medical facility with naloxone, training health care providers, and making naloxone available to veterans at risk for opioid overdose.[97] The OEND pilot programs have proved effective, and already the VA has recommended that facilities begin implementing OEND programs.[98] Providing the Director of the VA with the authority—or obligation—to implement OEND programs will ensure that OEND programs are quickly applied system-wide.

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92. Many states are leading the way in providing alternatives to incarceration. *See, e.g.*, HEROIN AND OPIOID EMERGENCY TASK FORCE, MD., FINAL REPORT 20–23 (2015) (recommending that the State of Maryland establish wrap-around service centers to help those on parole with addiction, expand the Segregation Addictions Program for those incarcerated with addictions, implement a more explicit probation and parole program for those with addiction, establish a recovery unit within state prisons, and implement a study on the consequences of Maryland laws and regulations on employment of ex-offenders).

93. S. 524 § 202.

94. *Id.* § 911.

95. *See* Mark Sullivan et al., *National Analysis of Opioid Use Among Veterans*, AM. ACAD. PAIN MED. (2014), http://www.painmed.org/2014posters/abstract-119/ (finding that 52.4% of veterans surveyed used opioids chronically).

96. S. 524 § 924.

97. *Id.* § 911(e)(1)(B)(ii).

98. *See* VA PHARMACY BENEFITS MANAGEMENT SERVS., VA, RECOMMENDATIONS FOR ISSUING NALOXONE KITS AND NALOXONE AUTOINJECTORS FOR THE VA OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION (OEND) PROGRAM 7 (2015) (proposing an expansion of the VA OEND program to provide naloxone to veterans at risk of opioid overdose).

Section 107 of CARA calls on HHS to oversee grants to improve co-prescribing of naloxone to individuals being prescribed prescription opioids who are "at elevated risk of overdose."[99] Grant money can be used for programming, training, tracking of co-prescribing practices, purchasing of naloxone, offsetting co-pays, conducting community outreach, and connecting with those who have experienced an overdose.[100] HHS would be required to perform a study of the effectiveness of the program and report the results of that study to Congress.[101]

Section 110 of CARA creates grants administered by HHS to develop standing orders for pharmacies to prescribe opioid overdose reversal medication; implement best practices for prescribing opioids for the treatment of chronic pain, co-prescribing naloxone with prescription opioids, and training patients to administer naloxone; and educate the public about naloxone.[102]

B. Overdose Prevention Act / Stop Overdose Prevention Stat Act of 2015

Senator Jack Reed (D-RI) and Representative Donna Edwards (D-MD) have introduced companion bills entitled the Overdose Prevention Act and the Stop Overdose Stat Act of 2015, respectively (collectively Overdose Prevention Act), which would create a taskforce administered by SAMHSA that would fund grants for a diverse number of organizations to purchase naloxone and create a taskforce that would recommend legislative and administrative actions.[103] It is important to note that the Overdose Prevention Act would also fund a CDC program to oversee trends in overdose deaths[104] and require NIDA to study overdose prevention methods, programs, and new formulations of naloxone.[105]

The Overdose Prevention Act authorizes $20 million annually for fiscal years 2016 through 2020 for SAMHSA to enter into cooperative agreements with "a State, local, or tribal government, a correctional

99. S. 524 § 107.

100. *Id.*

101. *Id.*

102. *Id.* § 110.

103. Overdose Prevention Act, S. 1654 § 3, 114th Cong. (2015); Stop Overdose Stat Act of 2015, H.R. 2850 § 3, 114th Cong. (2015).

104. S. 1654 § 3; H.R. 2850 § 3.

105. This type of research could lay the groundwork necessary for the FDA to reconsider whether naloxone should be reclassified as an over-the-counter drug. *See* S. 1654 § 4; H.R. 2850 § 4; *see infra* Part VI.A.1–2 (noting that to reclassify naloxone the FDA would need to go through a rigorous study of the efficacy of naloxone and overdose prevention programs).

institution, a law enforcement agency, a community agency, a professional organization in the field of poison control and surveillance, or a private nonprofit organization."[106] The Overdose Prevention Act requires funded organizations to do one or more of the following: educate prescribers and pharmacists about naloxone prescribing; train first responders, law enforcement officers, corrections officials, and other individuals on how to respond to an overdose; implement overdose prevention programming; or, educate the public about overdose prevention.[107] The Abuse Prevention Act would also require SAMHSA to establish a coordinating center that would collect, evaluate, and disseminate data from the grantees, as well as create best practices for each "type of community involved."[108]

Similar to the Abuse Prevention Act and CARA,[109] the Overdose Prevention Act would require HHS to convene a working group of representatives from at least nineteen agencies and organizations.[110] Unlike the Abuse Prevention's task force—which would be tasked with creating best practices for prescribing pain medication—the Overdose Prevention Act's task force would develop a public health campaign, create suggestions for expanding overdose prevention programming, and recommend legislative and administrative changes to improve access to naloxone.[111]

C. Opioid Overdose Reduction Act of 2015

The Opioid Overdose Reduction Act of 2015, introduced by Senator Edward Markey (D-MA) and Representative Richard Neal (D-MA), removes civil liability for health care professionals, volunteers, and citizens

106. S. 1654 § 3; H.R. 2850 § 3.

107. S. 1654 § 3; H.R. 2850 § 3.

108. Because the Overdose Prevention Act would fund a diverse number of groups—law enforcement, community groups, and medical providers—the best practices produced would potentially overlap with best practices developed by other agencies. *See* S. 1654 § 3; H.R. 2850 § 3; *see supra* Part III (discussing the new efforts of the ONDCP, SAMHSA, and the CDC that also incorporate developing best practices).

109. *See supra* Part V.A.

110. S. 1654 § 3; H.R. 2850 § 3 (listing as working group participants: individuals directly impacted by drug overdose, direct service providers who engage individuals at risk of a drug overdose, drug overdose prevention advocates, NIDA, The Center for Substance Abuse Treatment, the CDC, HHS, FDA, ONDCP, The American Medical Association, The American Association of Poison Control Centers, The Federal Bureau of Prisons, The Centers for Medicare & Medicaid Services, DOJ, The Department of Defense, the VA, first responders, law enforcement, State agencies responsible for drug overdose prevention, and other individuals with expertise relating to drug overdoses).

111. S. 1654 § 3; H.R. 2850 § 3.

who administer naloxone in good faith.[112] Section 7 of the bill provides protection from liability for laypeople so long as they are trained on when and how to administer naloxone, and the necessary steps to take after administering naloxone.[113] Section 4 of the Act would preempt state laws that provide lesser or no liability protections.[114] Because this bill ostensibly requires demonstration of proper training in the event of civil proceedings, education and the development of best practices would ensure the success of an across-the-board liability reduction.

D. Bills Requiring the FDA to Reconsider Naloxone's Classification

Two bills, the Increasing the Safety of Prescription Drug Use Act of 2015[115] (Increasing Safety Act), introduced by Senator Tom Udall (D-NM) and the Opioid Abuse Prevention and Treatment Act of 2015[116] (Opioid Abuse Prevention Act), introduced by Representative Bill Foster (D-IL), would require the FDA to review naloxone's current status as a prescription drug. Although similar in text, there are two major differences in the bills. The Increasing Safety Act asks the FDA to consider whether naloxone should be classified as a *behind-the-counter* drug, and the Opioid Abuse Prevention Act asks the FDA to consider whether naloxone should be classified as an *over-the-counter* drug.

If the FDA is spurred to reclassify naloxone as behind-the-counter by the Increasing Safety Act's reclassification provision, a pharmacist may be required to make an assessment of an individual before that individual purchases naloxone.[117] The purpose of making naloxone available over-the-counter is to encourage individuals to walk into pharmacies and discreetly purchase the drug,[118] defeating any advantage the Increasing

112. Opioid Overdose Reduction Act of 2015, H.R. 1821, 114th Cong. (2015); Opioid Overdose Reduction Act of 2015, S. 707, 114th Cong. (2015).

113. H.R. 1821 § 7; S. 707 § 7.

114. H.R. 1821 § 4; S. 707 § 4.

115. Increasing the Safety of Prescription Drug Use Act of 2015, S. 636 § 106, 114th Cong. (2015).

116. Opioid Abuse Prevention and Treatment Act of 2015, H.R. 3677 § 5, 114th Cong. (2015).

117. S. 636 § 106; *see* RHODE ISLAND DEP'T OF HEALTH, *supra* note 76 (discussing Rhode Island's law that allows certain health officials and pharmacists to prescribe naloxone to any layperson on behalf of a non-present doctor, which creates similar implications for current Rhode Island pharmacists who look to prescribe naloxone as for hypothetical pharmacists under a nationwide behind-the-counter regime implied by S. 636 § 106).

118. *See* Tessie Castillo, *Top 5 Reasons Why We Need Over-the-Counter Naloxone to Combat Drug Overdose*, HUFFINGTON POST (June 9, 2014), http://www.huffingtonpost.com/tessie-castillo/top-5-reasons-why-we-need_b_5475235.html (arguing that over-the-counter

Safety Act may create; the Opioid Abuse Act would succeed in forcing the FDA to consider proliferating systemic change.

One potential downside to the Opioid Abuse Act is that the FDA may answer Congress in the same way it has answered petitioners in the past; naloxone is simply better as a prescription medication.[119] In doing so, the FDA could be challenged in court if they fail to consider behind-the-counter classification as a middle ground or, alternatively, as a first step to full over-the-counter status.[120] However, given the limited legislative history present at the time this Comment was written, the Opioid Abuse Act, on its face, would provide no reason why the FDA would have to consider a behind-the-counter reclassification.[121]

VI. A NEW NALOXONE DISTRIBUTION REGIME

There are signs that the naloxone distribution regime is evolving,[122] most obvious is the passing of CARA.[123] In fact, a number of the presidential hopefuls acknowledged the need for a public health approach to solve the opioid overdose epidemic. Senator Bernie Sanders (I-VT) previously called attention to the skyrocketing price of naloxone;[124] Secretary Hillary Clinton

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naloxone is imperative because doctor's visits are a barrier to naloxone access, naloxone is safer and easier to use than other emergency medications, over-the-counter naloxone would create equity of access between states, many people can't afford naloxone, and the FDA can fast track over-the-counter naloxone).

119. *See* Statement, *HHS Drug Treatment Support*, *supra* note 51 (providing overview of an instance where the FDA denied a citizen petition requesting that the FDA make naloxone over-the-counter).

120. In that instance, the FDA's decision not to consider a behind-the-counter classification would likely receive arbitrary and capricious review. *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 51 (1983) (determining that the National Highway and Traffic Safety Administration acted arbitrarily and capriciously because the proposed "rule may not be abandoned without any consideration whatsoever of [an implicit alternative]").

121. *See* Opioid Overdose Reduction Act of 2015, H.R. 1821 § 5, 114th Cong. (2015) ("[FDA] shall conduct a review of naloxone to consider whether naloxone should . . . be available as an over-the-counter drug.").

122. SAMHSA released the Opioid Overdose Prevention Toolkit to equip communities and local government with materials to develop policies and practices to respond to opioid overdoses. SAMHSA, OPIOID OVERDOSE PREVENTION TOOLKIT, HHS Publ'n No. (SMA) 13-4742 (2013).

123. *See* Comprehensive Addiction and Recovery Act, S. 524, 114th Cong. (2016) (enrolled bill).

124. *See* Letter from Sen. Bernie Sanders et al. to Stephanie Rawlings-Blake, Mayor, City of Baltimore, Md. et al. (July 29, 2015) (calling for Mayor Rawlings and other local officials across the country to negotiate a lower price for naloxone with a pharmaceutical company).

proposed a drug policy that would allocate funds for purchase of naloxone;[125] Carly Fiorina took a strong favorable position while a Republican presidential candidate;[126] and Governor Chris Christie (R-NJ), after losing a friend to opioid overdose, has taken a stance in support of the recovery community.[127]

A. Reclassifying Naloxone as an Over-the-Counter Drug

The current naloxone distribution regime is a product of the limitations imposed by naloxone's status as a prescription drug. This subpart will describe the administrative levers that the FDA has to reclassify naloxone and argue that the FDA should act affirmatively to reclassify naloxone as an over-the-counter drug.

1. Levers to Alter Naloxone's Legal Status

Two FD&CA mechanisms—an NDA and a monograph—would allow the FDA to consider a reclassification of naloxone.[128] First, the FDA could reconsider naloxone's classification as a prescription drug through the NDA process.[129] In 1962, Congress amended the FD&CA by adding 505(d), which required pre-market approval of a drug by the Secretary of the FDA.[130] In general, an NDA requires the FDA to reexamine the drug and all the components of the NDA process.[131] The NDA process takes months

125. *See* Hillary Clinton, *Another View—Hillary Clinton: How We Can Win the Fight Against Substance Abuse*, N.H. UNION LEADER (Sept. 9, 2015), http://www.unionleader.com/apps/pbcs.dll/article?AID=/20150901/OPINION02/150909909/0/mobile&template=mobileart&template=printart (proposing to increase SABG funding, reduce barriers for reimbursement of addiction treatment through Medicare and Medicaid, and provide treatment in lieu of criminal sentencing).

126. *See* Jenna Johnson, *Carly Fiorina: 'Drug Addiction Shouldn't be Criminalized.'*, WASH. POST (May 4, 2015) (invoking criminal justice reform as a possible solution to preventing recidivism as a result of addiction).

127. *See* Jason Cherkis, *Chris Christie Negotiates Discount on Heroin Overdose Drug for New Jersey First Responders*, HUFFINGTON POST (June 4, 2015), http://www.huffingtonpost.com/2015/06/04/chris-christie-naloxone_n_7514566.html (discussing Governor Christie's negotiation with a naloxone manufacturer for a 20% discount).

128. *See* FDA, ROLE OF NALOXONE, *supra* note 23, at 180–81 (detailing the steps that the FDA would need to take to reclassify naloxone through either an NDA or a monograph).

129. *See* 21 U.S.C. § 355 (2012) (providing statutory requirements for new drug approval by the FDA); *see also* FDA, ROLE OF NALOXONE, *supra* note 23, at 180 (describing the NDA process as the most likely choice to reclassify naloxone).

130. Drug Amendment of 1962, 87 Pub. L. No. 781 § 102(c) (1962) (requiring that the drug be shown to be safe and effective by substantial evidence).

131. *See* FDA, ROLE OF NALOXONE, *supra* note 23 at 188 (describing how the FDA will

to complete, is proprietary in nature, is product specific, and the manufacturer-applicant must pay a user fee and submit potentially costly studies supporting the NDA.[132] An NDA can begin via manufacturer application or, less frequently, through a citizen's petition. NDAs are primarily started by manufacturers; however, manufacturers have no financial incentive to seek a change in naloxone status.[133]

The lack of motivation among the FDA and pharmaceutical manufacturers caused a stalemate. The FDA-manufacturer relationship is a form of agency capture outside of the traditional regulator–regulatee framework.[134] Although the FDA could act affirmatively through the drug approval process, it is rare that the FDA does so.[135] For example, the FDA has the authority to remove a drug from prescription-only status if that classification is "not necessary for the protection of the public health."[136]

"take a fresh look at [naloxone]" during an NDA by re-studying the chemistry, toxicology, microbiology, clinical pharmacology, and efficacy data, as well as considering social science and consumer data from both the United States and European countries).

132. *See* ANDREA LEONARD-SEGAL, FDA, NALOXONE EXPANDED ACCESS: OTC STATUS 13 (2012) (comparing the NDA and monograph processes); *see also* FDA, ROLE OF NALOXONE, *supra* note 23, at 164–73 (discussing the types of studies and data that an applicant might have to submit to support an NDA to reclassify naloxone).

133. A normal incentive for a pharmaceutical company to apply for an NDA is the potential for increased profit. However, the cost of completing an NDA, in an effort to reclassify naloxone, may be more than the profit raised from exploiting that new over-the-counter market for naloxone. *See* Maia Szalavitz, *Naloxone Debate: FDA Hears Testimony About Making an Overdose Antidote Nonprescription*, TIME (Apr. 13, 2012), http://healthland.time.com/2012/04/13/naloxone-debate-fda-hears-testimony-about-making-an-overdose-antidote-nonprescription/print/ ("Anti-Op, which would like to sell naloxone over-the-counter, estimated that the approval process would cost $10 to $20 million, an amount that could exceed the current market for the drug."). So instead, naloxone manufacturers have attempted to increase profits by targeting sales toward governments and by raising prices—neither of which directly increases access for those at-risk of overdose.

134. Agency capture is "where regulators within the bureaucracy have been influenced by organized special-interest groups to adopt policies that are out of line with the broad public interest." *See generally* Michael A. Livermore et al., *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337 (2013) (describing the phenomenon of agency capture and the role of oversight in preventing agency capture).

135. *See* Burris et al., *supra* note 13, at 339 ("In theory, the [FDA] could act affirmatively within the drug approval process on its own view of the public interest, but in practice this is a rare event."); *see also* Elisabeth Rosenthal, *For Drugs That Save Lives, a Steep Cost*, N.Y. TIMES (Apr. 26, 2014) (arguing that Great Britain's FDA-analog goes further than the FDA in weighing "the value of new . . . drugs," which allows Great Britain to negotiate cheaper pricing for drugs).

136. 21 U.S.C. § 353(b)(3) (2012) (providing discretionary authority to the Secretary to remove drugs subject to 21 U.S.C. § 355 (2012)). Given this discretionary language, a judicial challenge to the secretary's inaction on naloxone's classification would likely fail. *See Norton v. S. Utah Wilderness Ass'n.*, 542 U.S. 55, 66 (2004) (holding, first, that an agency cannot

However, "The FDA's assumed role as guarantor of patient welfare has made agency officials inappropriately cautious when guiding the review process."[137] As such, manufacturers—and their ability to exploit markets—drive the FDA process.[138]

To resolve this lack of incentive, the FDA has the ability to designate naloxone as an "orphan drug"[139] under the Orphan Drug Act.[140] The Orphan Drug Act allows the FDA to subsidize market failures, such as, in naloxone's case, the incomplete market problem.[141] Designating naloxone as an orphan drug would streamline the FDA approval process,[142] potentially provide grant funding,[143] and potentially provide tax breaks.[144] The language of the Orphan Drug Act provides that the FDA may apply the orphan drug designation to drugs for diseases affecting over 200,000 persons.[145] While "it is not at all clear, however, whether these subsidies,

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be compelled to act unless there is some non-discretionary, discrete act required by the controlling statute and, second, that the controlling statute at issue was "mandatory as to the object to be achieved, but it [left the agency] a great deal of discretion in deciding how to achieve it").

137. Anna B. Laakmann, *Collapsing the Distinction Between Experimentation and Treatment in the Regulation of New Drugs*, 62 ALA. L. REV. 305, 320 (2011).

138. *See* Burris et al., *supra* note 13, at 339 (explaining the FDA's mission as "serving the public interest," but criticizing the FDA for rarely using its affirmative authority and instead acting as a "passive responder to applications based on research largely designed, conducted and funded by the industry")

139. An orphan drug is a drug that has been developed to treat a specific, rare medical condition. As it relates to this discussion, an orphan drug is often not produced or under-produced by pharmaceutical companies because the cost of research, development, and FDA approval outweighs the potential profit of selling the drug to an inherently small market.

140. 21 U.S.C. § 360bb(a)(1) (2012) (stating that any drug manufacturer may request that the Secretary designate their drug as a drug for a rare disease or condition—i.e. an orphan drug).

141. The high cost has drawn the attention of many legislators who have called on states to negotiate with naloxone manufacturers for cheaper prices. *See* Letter from Senator Bernie Sanders, *supra* note 124; *see also* Burris et al., *supra* note 13 at 337 (2009) ("The Orphan Drug Act provides significant economic incentives and regulatory support . . . ."); Rosenthal, *supra* note 135 (examining the high cost of alternatives to injectable naloxone and comparing the FDA's approval system to more efficient European models).

142. While NDA and monograph procedures are extensive and time consuming, the Orphan Drug Act allows the FDA to assist manufacturers in research and data collection allowing potential manufacturers to capture a growing market. *See generally* 21 U.S.C. § 360ee (2012).

143. *See id.* § 360ee(a) (stating that grants to manufacturers of naloxone would subsidize losses incurred during testing and development of new formulations of naloxone).

144. *See* 26 U.S.C. § 45C (2012) (providing "credit . . . equal to 50 percent of the qualified clinical testing expenses for the taxable year.").

145. *See* 21 U.S.C. § 360bb(a)(2) (providing potential designations to drugs for a disease

even if applicable, are sufficient to motivate commercial pharmaceutical companies to act,"[146] naloxone may provide commercial pharmaceutical companies with a profitable and (unfortunately) large market. In fact, Suboxone, a combination of naloxone and buprenorphine that is used to treat opioid addiction, was given orphan drug status.[147]

An NDA process can also begin after a citizen, corporation, or non-profit organization files a citizen's petition.[148] A citizen's petition, if accepted, would allow the FDA to begin the NDA process.[149] On May 27, 2014, Pharmacists Planning Service, Inc. submitted a citizen's petition to ask the FDA to reclassify naloxone as a behind-the-counter drug.[150] On March 31, 2015, the FDA denied Pharmacists Planning Service, Inc.'s petition.[151] In *Heckler v. Chaney*,[152] the Supreme Court of the United States held that judicial review of agency nonenforcement is presumptively not available.[153] Justice Brennan's concurring opinion suggested exceptions to this presumption of unreviewability when the agency "flatly claims that it has no statutory jurisdiction to reach certain conduct, . . . engages in a pattern of nonenforcement of clear statutory language, . . . refuse[s] to enforce a regulation, . . . or . . . violates constitutional rights . . . ."[154] In this

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that "affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug").

146. Burris et al., *supra* note 13, at 338.

147. *See* FDA, CUMULATIVE LIST OF DESIGNATED ORPHAN DRUG PRODUCTS 11 (2008). (providing that Suboxone was designated an orphan drug on October 27, 1994).

148. *See* Citizens Petition, 21 C.F.R. § 10.30 (2015) (providing the administrative procedures under which a citizen may petition the FDA to issue, amend, or revoke an FDA classification).

149. *See Choosing a Regulatory Pathway for Your Drug*, FDA (2013), http://www.accessdata.fda.gov/scripts/cder/training/OTC/topic5/topic5/index05.htm (last visited April 20, 2016) ("The Citizen Petition . . . Process can be used to request FDA to amend an OTC drug monograph at any phase of its development and after publication of a final monograph.").

150. FDA, FDA-2014-P-0752-0002, CITIZEN PETITION FROM PHARMACISTS PLANNING SERVICE INC. (May 27, 2014) (requesting that the FDA issue a federal regulation to place naloxone behind the pharmacy counter in addition to prescription use).

151. FDA, FDA-2014-P-0752-0003, PETITION DENIAL LETTER FROM FDA CDER TO PHARMACISTS PLANNING SERVICE INC. PPSI (2015) [hereinafter PETITION DENIAL LETTER] (denying the petition because the request did not meet the requirements of §503(b)(3) of the FD&CA or demonstrate that naloxone is safe or effective without the supervision of licensed healthcare official).

152. 470 U.S. 821 (1985).

153. *Id.* at 827 (holding that the FDA's decision not to take enforcement actions requested by respondents was not subject to review under the APA).

154. *Id.* at 839 (Brennan, J., concurring).

instance, none of Justice Brennan's exceptions to the assumption of unreviewability of nonenforcement decisions apply because the FDA is well within the bounds of the Citizen Petition provision to deny the petition[155] and has already provided reasons why naloxone should be classified as a prescription drug.[156]

Second, the FDA can begin a notice-and-comment rulemaking process known as a monograph.[157] The FDA passed regulations[158] establishing the monograph process to categorize unapproved products based on pre-approved sets of ingredients.[159] The benefit of a monograph process is that it requires no user fees and any manufacturer may use the monograph to produce the drug.[160] A monograph is a three-part public notice-and-comment rulemaking procedure.[161] Initially, an advisory review panel analyzes the active ingredients and proposes labeling for a product.[162]

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155. *See* Henley v. FDA, 77 F.3d 616, 620 (2d Cir. 1996) (finding that the FDA's denial of a citizen's petition is arbitrary and capricious if the agency relied on factors outside the scope of its congressional authority, failed to consider important aspects of the problem, provided an irrational basis for its decision, or failed to apply agency expertise) (citing Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983)).

156. *Compare* 21 CFR § 314.93(e)(1)(iv) (2015) (stating that the FDA may deny a petition if it finds that "any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem . . . ."), *with* PETITION DENIAL LETTER, *supra* note 151, at 2 ("[Y]ou have not provided studies or other scientific evidence showing that the drugs are safe and effective for use without supervision of a licensed healthcare practitioner or under the supervision of a pharmacist.").

157. *See* FDA, ROLE OF NALOXONE, *supra* note 23, at 181 (explaining that the monograph process could be used to reclassify naloxone).

158. 21 C.F.R. § 330.10 (1981) (establishing the procedural guidelines and regulations for classifying over-the-counter drugs as drugs commonly recognized by experts as safe and effective for use and not as misbranded).

159. *See* Cutler v. Hayes, 818 F.2d 879, 882–85 (1987) (providing a succinct overview of the early development of the monograph process); *see also* James Yeagle, *Nanotechnology and the FDA*, 12 VA. J.L. & TECH., no. 6, 2007, at 12 (explaining that the FDA categorized hundreds of unapproved drugs and then defined approved sets of ingredients for each of the groups).

160. *Difference: NDA Process and OTC Monograph Process*, FDA, http://www.accessdata.fda.gov/scripts/cder/training/OTC/topic3/topic3/da_01_03_0190.htm (last visited April 13, 2016) (reviewing the NDA approval process and the OTC monograph process including distinctions that the final monograph is open to anyone and there are no user fees in the OTC monograph process).

161. *Over-the-Counter (OTC) Drug Monograph Process*, FDA (Jan. 1, 2015), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm317137.htm (last visited Apr. 13, 2016). (explaining that the three-part rulemaking procedure results in the establishment of standards like drug monographs for an OTC therapeutic drug class).

162. *See id.* (explaining that a panel is charged with reviewing active ingredients in OTC drug products to determine whether they are safe and effective for self-treatment by labeling

Then the panel publishes its conclusions in the Federal Register as an advanced notice of proposed rulemaking, and interested parties submit their comments and data in response to the proposed rule.[163] From there, the FDA reviews the "active ingredients in each class of drugs" and publishes a tentative monograph in the Federal Register based on its initial assessment, "on public comment, and on new data that may have become available."[164] Finally, the FDA reviews new comments on the tentative final monograph and publishes the final rule.[165]

2. Overcoming Market Failures

The FDA should move immediately to reconsider naloxone's current classification as a prescription drug and position in Section (b) of the FD&CA through an NDA.[166] There are only two ways that this could happen. First, Congress could pass a resolution committing the FDA to investigating the validity of such a reclassification through the NDA process. In drafting the bill, Congress should defer to the FDA's expertise and include both behind- and over-the-counter language from the Increasing Safety Act and the Opioid Abuse Prevention Act, respectively.[167] Second, as discussed in Part II, the Administrator of the FDA could begin an NDA review, but this statutory authority has rarely been used.[168] Nevertheless, proactive action from the FDA would be preferable because neither congressional nor third-party action is guaranteed.[169]

The FDA's coordination with SAMHSA, the CDC, and the ONDCP would allow the FDA to act to evaluate naloxone's status more quickly because at least part of the FDA's reconsideration process is to examine

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them into three categories).

163. *See id.* (explaining that the categories that are concluded for each active ingredient in the OTC drug products are then published in advance for further review).

164. *See id.*

165. *See id.* (stating that a publication is the final phase of the review process, but the monograph can be amended upon the Commissioner's own initiative or upon petition by any interested person).

166. An NDA would be more efficient than a monograph because a monograph requires a multi-part publishing process that takes years. *See* 21 U.S.C. § 353(b) (2012).

167. Opioid Abuse Prevention and Treatment Act of 2015, H.R. 3677 § 5, 114th Cong. (2015); Increasing the Safety of Prescription Drug Use Act of 2015, S. 636 § 106, 114th Cong. (2015).

168. *See* Burris et al., *supra* note 13, at 339 ("In theory, the [FDA] could act affirmatively within the drug approval process on its own view of the public interest, but in practice this is a rare event.").

169. Nor are third-party petitions guaranteed to succeed. *See* PETITION DENIAL LETTER, *supra* note 151.

social science and new data regarding the efficacy and value of a drug since its initial classification.[170] The President could use an executive order[171] to create a temporary working group made up of representatives from various administrative agencies.[172] This group could coordinate to collect and produce data to support the FDA's examination of naloxone's reclassification.[173] In the event that the President determines this path is politically problematic,[174] the Secretary of HHS should issue a guidance document to bring the various agencies housed within HHS in line with the President's policy objective.[175]

The reclassification of naloxone would have three main consequences. First, individuals at risk of overdose and laypeople would be more likely to carry naloxone. Visiting a health care professional is a major barrier for individuals who might otherwise purchase naloxone.[176] Second, naloxone would be cheaper than it is currently because the market for the drug would increase.[177] Third, education and training would become essential to

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170. *See* FDA, ROLE OF NALOXONE, *supra* note 23, at 188 (discussing concerns and data gaps that would need to be addressed if the FDA was to begin an NDA).

171. *See* U.S. CONST. art. 2, § 3, cl. 5 (generally providing the power to issue executive orders).

172. *See generally* FREEMAN & ROSSI, ADMIN. CONF., *supra* note 10, at 4 (discussing a broader coordinating body and recommending new executive order to encourage agency coordination through an all-inclusive oversight plan).

173. *See id.* at 8 (arguing that the President should encourage interagency teams "to produce and analyze data together").

174. *See* Elaine Pawlowski, *Addiction Stigma Interferes with Legislation*, HUFFINGTON POST (Apr.11, 2014 1:51 PM), http://www.huffingtonpost.com/elaine-pawlowski/addiction-stigma-interfer_b_5118191.html (expressing the stigma associated with drug use as a barrier to the creation of effective addiction treatment legislation). *But see supra* notes 124–127 and accompanying text (detailing former presidential candidates' positive stance on addiction-related issues).

175. A guidance document from HHS could encourage the ONDCP, SAMHSA, and the CDC to work together to develop and share data regarding their naloxone distribution programs. If this guidance document includes any legal interpretation, "the weight of deference afforded to [it] depends upon 'the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade.'" Univ. of Tex. Sw. Med. Ctr. v. Nassar, 133 S. Ct. 2517, 2533 (2013) (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

176. *See* Eric P. Brass, *Changing the Status of Drugs from Prescription to Over-the-Counter Availability*, 345 NEW ENG. J. MED. 810, 812 (2001).

177. Zachary Brennan, *OTC Opioid Overdose Antidote: Why Is It Not FDA Approved?*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Feb. 24, 2016), http://www.raps.org/Regulatory-Focus/News/2016/02/24/24400/OTC-Opioid-Overdose-Antidote-Why-is-it-not-FDA-Approved/ (explaining that a 4,000% price hike in naloxone is the result of a lack of competition between naloxone producers).

the success of an effective overdose prevention blueprint.[178] Education can range from teaching opioid prescribers or parents how to identify the signs of addiction to coaching police officers to refer those with a substance use disorder to treatment. Intimately tying naloxone interventions to access to treatment will ensure the long-term success of combatting the opioid overdose epidemic.[179]

B. Increasing Funding for Naloxone Distribution

Congress should allocate funds for the purchase of naloxone. CARA and proposed bills attack the funding issue from a number of angles.[180] CARA calls on the United States Attorney General to oversee grants to state, local, and tribal governments for law enforcement agencies and first responders to purchase naloxone.[181] CARA also calls on HHS to administer grants to expand access to naloxone through co-prescribing practices.[182] The Overdose Prevention Act would require SAMHSA to operate cooperative agreements with a wide variety of agencies to fund the purchase of naloxone for pharmacists, first responders, law enforcement officers, and those at risk of opioid overdose.[183]

While the role of law enforcement agencies is crucial in the fight to prevent opioid overdoses, Department of Justice (DOJ) oversight of grants to increase access to naloxone amongst law enforcement agencies and first responders presents some issues. Until recently, many police agencies resisted the use of naloxone for funding, policy, or political reasons.[184] The

178. *See generally* MASS. DEPT. OF PUB. HEALTH, MDPH NALOXONE PILOT PROJECT CORE COMPETENCIES (2012), http://www.mass.gov/eohhs/docs/dph/substance-abuse/core-competencies-for-naloxone-pilot-participants.pdf (providing an overview of Massachusetts's very effective OEND program that incorporates public education).

179. *See* Tyler Bell, *Naloxone Necessary for Heroin Epidemic, but Not a Solution*, CHARLESTON DAILY MAIL (Apr. 13, 2015), http://www.wvha.org/Media/NewsScan/2015/April/4-13-Naloxone-necessary-for-heroin-epidemic,-but-n.aspx (explaining that once resuscitated, individuals with substance abuse disorders need to be able to access treatment).

180. *See* Comprehensive Addiction and Recovery Act, S. 524, 114th Cong. (2016) (enrolled bill).

181. Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015, H.R. 2805 § 7, 114th Cong. § 7 (2015); Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015, S. 1134 § 7, 114th Cong. § 7 (2015).

182. S. 524 § 202.

183. S. 1654 § 3; H.R. 2850 § 3.

184. *See, e.g.*, Matt Faye, *OD Antidote Not Catching on with Many Westmoreland Police Departments*, TRIB TOTAL MEDIA (Sept. 9, 2015, 10:45 PM), http://triblive.com/news/westmoreland/ 8832255-74/police-officers-antidote (outlining the concerns of a local police department as a local government considers a naloxone program).

DOJ's Law Enforcement Naloxone Toolkit strived to end this outlook.[185] Nevertheless, police walk a fine line when reporting to the scene of an overdose because it is likely that heroin will be present, and because some individuals at the scene may be on probation or supervised release.[186] The growing popularity of Good Samaritan laws requires many police and prosecutors to disregard the possession of small amounts of illicit opioids.[187] The diversity of local and state liability reduction laws and Good Samaritan laws muddies the water when entrusting the DOJ with coordinating a nationwide effort to increase not only the access to naloxone but also the public's willingness to call 9-1-1.[188]

Grants for the purchase of naloxone given to first responders should be administered in conjunction with first responders through the CDC. The proposal of the Overdose Prevention Act, which establishes cooperative agreements, would allow the CDC to collate data regarding overdose deaths with data produced as a result of naloxone programs created by the cooperative agreements.[189] The traditional role of the CDC is to study the causes and implications resulting from diseases.[190] This expertise and mission would produce outstanding results in developing both law enforcement and first responder best practices.

Furthermore, the scope of the Overdose Prevention Act's cooperative agreement provision is very appealing. The most expansive naloxone funding program proposed, the Opioid Prevention Act, would allow a multi-tier and multi-front approach to arming communities with naloxone.[191] In sparsely populated regions, it may be more important to increase access to naloxone directly for at risk populations. In urban

185. *See* DOJ, ATTORNEY GENERAL HOLDER ANNOUNCES PLANS FOR FEDERAL LAW ENFORCEMENT PERSONNEL TO BEGIN CARRYING NALOXONE (2014).

186. *See* Lynn Arditi, *Despite the Good Samaritan Law, Some Addicts Still Punished for Seeking Help*, PROVIDENCE J. (Apr. 9, 2014, 12:56 PM), http://www.providencejournal.com/topics/special-reports/overdosed/20140409-despite-the-good-samaritan-law-some-addicts-still-punished-for-seeking-help-video.ece (detailing the story of Veronica Cherwinski who was arrested for felony drug charges despite Rhode Island's Good Samaritan law).

187. *See* Bissonnette, *supra* note 68, at 460 (arguing that 9-1-1 immunity laws should prohibit police from taking people into custody, not just protection from prosecution).

188. *See Drug Overdose Immunity and "Good Samaritan" Laws*, NAT'L CONFERENCE OF STATE LEGISLATURES (2015) (describing most 9-1-1 immunity laws as providing immunity to criminal offenses relating to naloxone and low-level possession of illicit drugs).

189. S. 1654 § 3; H.R. 2850 § 3.

190. *See supra* part III.C.

191. *See* S. 1654 § 3 (providing funding to: educate prescribers and pharmacists about naloxone prescribing; train first responders, law enforcement officers, corrections officials, and other individuals on how to respond to an overdose; implement overdose prevention programming; or educate the public about overdose prevention); H.R. 2850 § 3.

centers, first responders and law enforcement may be on the front line. The flexible and comprehensive nature of analyzing data from a diverse group of grantees will be key to the long-term success of such a public health intervention because agencies could develop best practices tailored to specific circumstances.

The Jason Simcakoski Act, which merely calls on the VA to expand the OEND without additional funding specifically for that purpose, could be improved by allotting funds specifically to expand the VA's OEND programs.[192] In addition to having a positive effect on the VA's practices, an expansion of the OEND could be replicated in civilian emergency rooms and hospitals. While not proposed by any of the current bills, funding for prescribing naloxone to individuals immediately preceding an individual's release from the emergency room after an overdose would be an effective strategy to prevent reoccurring overdoses. The OEND program would be valuable to study the efficacy of co-prescribing practices and of best practices for treatment referral in a controlled and replicable manner.[193] A more robust effort to incorporate naloxone into doctors' offices would serve to complement attempts to curb overprescribing of opioids.

C. The Inter-Agency Opioid Overdose Prevention Taskforce

The need for successful cooperation between SAMHSA, CDC, DOJ, and other agencies transcends each agency's potential individual success in increasing access to and use of naloxone interventions. The opportunity for successful cooperation between these federal agencies would encompass many other qualitative goals including the success of state and local agencies' efforts to prevent opioid overdoses, the creation of clear frontline coordination, and the protection of various civil rights and liberties. The creation of the Inter-Agency Opioid Overdose Prevention Taskforce (Prevention Taskforce) would enhance interagency cooperation and coordination.[194]

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192. S. 524 § 301.

193. *See* Oral Testimony, *Examining Legislative Proposals, supra* note 3 (statement of Dr. Robert Corey Waller, Chair, Legislative Advocacy Committee of the American Society of Addiction Medicine) (explaining that co-prescribing naloxone along with prescription opioids is a key component to expanding access to naloxone).

194. The President may also consider appointing an Opioid Czar to coordinate overdose prevention policy. The President's power to name policy advisors—dubbed czars—is largely accepted. *See* Aaron J. Saiger, *Obama's "Czars" for Domestic Policy and the Law of the White House Staff*, 79 FORDHAM L. REV. 2577, 2608 (2011) (indicating that there is clear

The President has the authority to issue an executive order to establish the Prevention Taskforce to coordinate efficient action among the administrative agencies.[195] Alternatively, though much more difficult to achieve, Congress could pass legislation creating the Taskforce and supporting the agencies through appropriations, altering of missions or goals, or holding oversight hearings. Yet, the President is in a unique and flexible position to coordinate a policy change.[196]

The President should give the Prevention Taskforce three general tasks.[197] First, drawing from CARA,[198] the Taskforce should develop best practices to ensure effective referral to treatment, as well as reduce liability for both laypeople and first responders administering naloxone.[199] Second, akin to the Overdose Prevention Act's requirement that SAMHSA work with grantees to develop best practices for corresponding organizations, the Taskforce should develop best practices for training, equipping, and maintaining agency, state, and local efforts to increase the use of naloxone.[200] Third, the Taskforce should adopt the language of the Overdose Prevention Act and recommend legislation and regulations that would act in concert to fund and shape opioid overdose prevention policies in the future.[201] Although the strain between Congress and the Administration has been well documented, ONDCP Director Botticelli has echoed the growing ground for collaboration by describing opioid overdose

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consensus that the President may delegate policymaking authority to Executive Office Czars). President Obama has largely relied on the ONDCP Director—the Drug Czar—to serve as the face of opioid policy. *See infra* part III.A (arguing that the role of the ONDCP is evolving, but that the ONDCP may be limited by its enabling statute); *see also* Jose Villalobos & Justin Vaughn, *More Czars than the Romanovs? Obama's Czars in Historical and Legal Context*, ANN. CONF. OF THE AM. POL. SCI. ASS'N 8 (2010) (explaining that modern presidents have used "strategies of centralization" to reclaim authority over the actions and policies of the administrative state).

195. *See* Freeman & Rossi, ADMIN. CONF., *supra* note 10, at 4 (discussing the President's authority to issue executive orders to coordinate and manage agency action); s*ee also* Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 587–88 (1952) (holding that an executive order must be based on a constitutional grant of power or execution of congressional policy, which would likely be present in the statutes of HHS, CDC, and FDA).

196. *See* Freeman & Rossi, *Agency Coordination*, *supra* note 10, at 1197 ("the President is amply equipped to promote coordination through various tools already described, including a number of White House policy offices, councils, and special advisors through which he might exert strong, centralized oversight of agency policymaking and implementation.").

197. *See generally* Freeman & Rossi, *Agency Coordination*, *supra* note 10 (providing general guidance for the President to effectuate effective agency action).

198. S. 524 § 202.

199. *See* S. 1654 § 3; H.R. 2850 § 3.

200. S. 1654 § 3; H.R. 2850 § 3.

201. S. 1654 § 3; H.R. 2850 § 3.

as a topic in which "administration priorities and congressional priorities are aligned."[202]

To accomplish these goals, the President—through executive memorandum or executive order—could push members of the Prevention Taskforce to sign a Memorandum of Understanding (MOU).[203] This would allow the various agencies to draw lines between specific target groups and tasks, establish metrics as well as procedures for reporting and disseminating data, and commit to reaching certain funding and policy goals. Coordination through the Executive is necessary to ensure agencies negotiate, implement, and act on the MOU because MOUs are generally not legally enforceable.[204] In this way, an MOU is flexible and easily altered as the landscape of the opioid overdose epidemic changes over time.[205]

The MOU could state that member agencies must collaborate when developing best practices for naloxone grant money recipients, produce data sets relating to opioid overdose, and promulgate rules affecting the distribution or use of naloxone.[206] The effect of required cooperation would be uniform and predictable information that would improve state-response as well as the creation of data that the FDA could use to reclassify naloxone as an over-the-counter drug.

Alternatively, Congress could require mandatory consultation by

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202. *Examining Legislative Proposals to Combat Our Nation's Drug Abuse Crisis: Hearing Before the Subcomm. on* Health of the H. Comm. on Energy and Commerce, 114th Cong. (2015) (statement of Dir. Botticelli, ONDCP).

203. Unlike congressional action, which would be mandatory given proper drafting, an executive memorandum would rely on presidential clout but would ultimately be left up to the agency. *See* Todd F. Gaziano, *The Use and Abuse of Executive Orders and Other Presidential Directives*, 5 TEX. REV. L. & POL. 267, 311 (2001) (discussing the types of executive orders and potential judicial review).

204. *See* Freeman & Rossi, *Agency Coordination*, *supra* note 10, at 1165 n.159 ("Courts have hinted that [memorandums of understandings] MOUs can create substantive obligations for agencies even when they are not promulgated through notice-and-comment rulemaking, but such suggestions seem fairly rare.") (referencing High Country Citizens' All. v. Norton, 448 F. Supp. 2d 1235, 1249–50 (D. Colo. 2006)).

205. *See* FREEMAN & ROSSI, ADMIN. CONF., *supra* note 10 at 8 (recommending that coordinating agencies sign MOUs with sunset provisions so that agencies regularly determine if the MOUs are of value).

206. *See generally* Nat'l Mining Ass'n v. McCarthy, 758 F.3d 243 (D.C. Cir. 2014) (quoting *Sierra Club v. Costle*, 657 F.2d 298, 406 (D.C. Cir. 1981) ("When considering consultations among Executive Branch officers, our 'form of government simply could not function effectively or rationally if key executive policymakers were isolated from each other and from the Chief Executive. Single mission agencies do not always have the answers to complex regulatory problems' and need 'to know the arguments and ideas of policymakers in other agencies as well as in the White House.'").

member agencies with the Prevention Taskforce.[207] Benefits of congressional action would be the efficient use of shared resources, clearly defined roles for member agencies, built-in congressional oversight provisions, and statutorily enforced requirements that the ONDCP, SAMHSA, and the CDC share data regarding their naloxone programs.[208]

The Secretary of HHS should be appointed to oversee the Prevention Taskforce like the taskforce recommended by the Opioid Abuse Prevention Act.[209] HHS would be best suited to oversee this taskforce because of its relationship with community health organizations and medical professionals. The taskforce should also be required to publish a set of best practices for naloxone training, develop a public education program, suggest administrative and legislative changes, and collect data for state and local organizations to improve outreach and response.

CONCLUSION

The tide of political pressure is beginning to turn in favor of treating opioid overdose as a public health problem rather than a crime problem. States are doing the heavy lifting in finding creative solutions to overcome naloxone's classification as a prescription drug. Federal agencies are beginning to recognize the role that naloxone could play and are incorporating naloxone programs into their agency goals. However, there is more work to be done. The President should establish the Inter-Agency Opioid Overdose Prevention Taskforce. Congress should expand on the funding provisions of CARA by directing funding directly to communities with little access to medical care. The FDA should reclassify naloxone as an over-the-counter drug. These changes would usher in a new naloxone distribution regime and ultimately reduce the staggering number of opiate overdoses afflicting our country.

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207. Freeman & Rossi, *Agency Coordination*, *supra* note 10, at 1158 (citing Bennett v. Spear, 520 U.S. 154, 169 (1997)) ("Although the action agency retains considerable discretion, in practice this provision can function as a veto because disregarding recommendations can expose an agency to civil and criminal penalties and because deviation may render a decision arbitrary and capricious on judicial review.").

208. Shared data could cover best practices, efficacy of intervention programs, and outcomes. *See* SUNDARARAMAN, *supra* note 52, at 7 (calling for more statutory requirements that SAMHSA work with the CDC and other agencies in order to increase efficiency).

209. *See* H.R. 2805 §§ 3, 7; S. 1134 §§ 3, 7.

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